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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/645,656	08/25/00	SCHOLKENS	0 02481.1702

022852 H#22/0620  
FINNEGAN, HENDERSON, FARABOW, GARRETT &  
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WASHINGTON DC 20005

EXAMINER

BAHAR, M

ART UNIT	PAPER NUMBER
1617	6

DATE MAILED:

06/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

JUN 22 2001

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Docketed 62101 Attorney 3001505  
Case 2481.1702  
Due Date 9-20-01 w/EXT  
Action RESPONSE  
By 3

## Office Action Summary

Application No.	Applicant(s)	
09/645,556	SCHOLKENS ET AL.	
Examiner	Art Unit	
Mojdeh Bahar	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1)  Responsive to communication(s) filed on \_\_\_\_\_.
- 2a)  This action is FINAL.      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4)  Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 1-17 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.
- 12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All b)  Some \* c)  None of:
    1.  Certified copies of the priority documents have been received.
    2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- 15)  Notice of References Cited (PTO-892)
- 16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 & 5.
- 18)  Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 19)  Notice of Informal Patent Application (PTO-152)
- 20)  Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specifically named ACE inhibitors, does not reasonably provide enablement for "pharmaceutically acceptable derivatives" of the ACE inhibitors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The specification does not provide guidance as to which ACE inhibitor derivatives are useful in the claimed method. Moreover, the specification does not set out criteria for one of ordinary skill in the art to be able to distinguish those derivatives that would be useful in the instant method from those that would not be useful. One of ordinary skill in the art would have to perform undue experimentation in order to identify which derivatives of ACE inhibitors would be useful in the claimed method.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms "normal" and "low" in claim 2 is a relative term which renders the claim indefinite. The terms "normal" and "low" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. One of ordinary skill in the art would not know how to define normal, neither would one of ordinary skill be able to ascertain the limits of the term "low". Note that, but for subject matter of an issued US patent, essential subject matter cannot be incorporated by reference into claims.

*Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,2,5-6,10-12 and 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Sudilovsky (EP 0474438 A1).

Sudilovsky (EP 0474438 A1) discloses employing a composition comprising ceronapril in a method of preventing the onset of cerebrovascular disease such as stroke in a normotensive patient in an amount of 0.5 mg to about 30 mg per day, see particularly claims 4,7 and 11 as well as page 2 lines 8-11.

Claims 3, 7 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Tschollar (EP 0426066 A2).

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Tschollar (EP 0426066 A2) discloses the use of an ACE inhibitor for preparing a pharmaceutical composition for preventing onset of type II diabetes in a mammalian species, see claim 1. Tschollar (EP 0426066 A2) further discloses captopril, zofenopril, ceranapril, fentiapril and fosinopril, enalapril and lisinopril as suitable ACE inhibitors, see particularly claims 7-11.

Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Maclaughlan et al. (WO 96/24373).

Maclaughlan et al. (WO 96/24373) discloses the employment of ACE inhibitors in a co-therapy in patients susceptible to congestive heart failure, see particularly claims 1-5, 9 and 11.

Claims 14 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by FDA Orange Book Active Ingredient Detail Record Search.

FDA Orange Book Active Ingredient Detail Record Search discloses a pharmaceutical composition comprising candesartan cilexetil as the active ingredient.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tschollar (EP 0426066 A2).

Tschollar (EP 0426066 A2) teaches the use of an ACE inhibitor for preparing a pharmaceutical composition for preventing onset of type II diabetes in a mammalian species, see

claim 1. Tschollar (EP 0426066 A2) further discloses captopril, zofenopril, ceranapril, fentiapril and fosinopril, enalapril and lisinopril as suitable ACE inhibitors, see particularly claims 7-11.

Tschollar (EP 0426066 A2) does not teach the employment of the particular ACE inhibitors recited in the claims in its method of preventing onset of type II diabetes.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ any of the ACE inhibitors recited in the instant claims in Tschollar's (EP 0426066 A2) method of preventing the onset of type II diabetes.

One of ordinary skill in the art would have been motivated to substitute any of the ACE inhibitors recited in the instant claims for captopril, zofenopril, ceranapril, fentiapril and fosinopril, enalapril and lisinopril discussed particularly in Tschollar because based on this reference, all ACE inhibitors would have been reasonably expected to have similar therapeutic effects in a method of preventing the onset of type II diabetes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from 8:30 a.m. to 6:30 p.m. Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar  
Patent Examiner

Application/Control Number: 09/645,556  
Art Unit: 1617

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June 8, 2001.

*Minna Moezie*  
MINNA MOEZIE, J.D.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

+ In the IDS

<b>Notice of References Cited</b>	Application/Control No.	Applicant(s)/Patent Under Reexamination	
	09/645,556	SCHOLKENS ET AL.	
	Examiner	Art Unit	Page 1 of 1
Mojdeh Bahar,		1617	

**U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US- -			
	B	US- -			
	C	US- -			
	D	US- -			
	E	US- -			
	F	US- -			
	G	US- -			
	H	US- -			
	I	US- -			
	J	US- -			
	K	US- -			
	L	US- -			
	M	US- -			

**FOREIGN PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
*	N	EP-0474438-	03-1992	GB	Sudilovsky	-- --
*	O	EP-0426066-	05-1991	US	Tschollar	-- --
*	P	WO-96/24373-	08-1996		McLaughlin et al.	-- --
	Q	- -				
	R	- -				
	S	- -				
	T	- -				

**NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	FDA Orange Book Active Ingredient Detail Record Search, June 1998.
	V	
	W	
	X	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

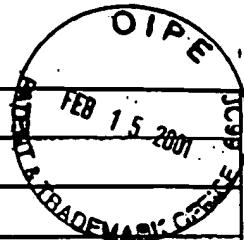
09/108701

*Applicant's Copy*

OMB No. 0651-0011

**INFORMATION DISCLOSURE CITATION**  
(Use several sheets if necessary)

Atty. Docket No.	02481.1702	Serial No.	09/645,556
Applicant	Unnamed		
Filing Date	August 25, 2000	Group:	1615



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Examiner Initial*	Document Number	Date	Name	Class	Sub Class	Filing Date If Appropriate
WBS	5,202,322	13 Apr 1993	Allen et al.			
	5,219,856	15 June 1993	Olsen			
	5,554,625	10 Sept. 1996	Rivero et al.			RECEIVED
	5,827,863	27 Oct. 1998	Almansa et al.			
	5,506,361	09 Apr. 1996	Koh et al.			FEB 16 2001
	5,470,975	28 Nov. 1985	Atwal			
WZ	5,554,624	10 Sept. 1996	Almansa et al.			TECH CENTER 1600/2000

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	Document Number	Date	Country	Class	Sub Class	Translation Yes or N
WBS	EP 0 331 014	06 Sept. 1989	Europe			
	WO 92/10188	25 June 1992	PCT			
	EP 0 474 438	11 Mar. 1992	Europe			
	EP 0 426 066	08 May 1991	Europe			
	WO 96/24373	15 Aug. 1996	PCT			
	WO 94/07492	14 Apr. 1994	PCT			
	GB 2 171 103	20 Aug. 1986	Great Britain			
	EP 0 292 923	30 Nov. 1988	Europe			
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Examiner	Derwent Abstract of EP 0 331 014	Date Considered	02/27/01
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*Applicant Copy*

Active Ingredient: CANDESARTAN CILEXETIL  
Dosage Form;Route: Tablet; Oral ||  
Proprietary Name: ATACAND  
Applicant: ASTRAZENECA  
Strength: 4MG  
Application Number: 020838  
Product Number: 001  
Approval Date: Jun 04, 1998  
Reference Listed Drug No  
RX/OTC/DISCN: RX  
TE Code:

Patent and Exclusivity Info for this product: [Click Here](#)

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Active Ingredient: CANDESARTAN CILEXETIL  
Dosage Form;Route: Tablet; Oral  
Proprietary Name: ATACAND  
Applicant: ASTRAZENECA  
Strength: 8MG  
Application Number: 020838  
Product Number: 002  
Approval Date: Jun 04, 1998  
Reference Listed Drug No  
RX/OTC/DISCN: RX  
TE Code:

Patent and Exclusivity Info for this product: [Click Here](#)

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Active Ingredient: CANDESARTAN CILEXETIL  
Dosage Form;Route: Tablet; Oral  
Proprietary Name: ATACAND  
Applicant: ASTRAZENECA  
Strength: 16MG  
Application Number: 020838  
Product Number: 003  
Approval Date: Jun 04, 1998  
Reference Listed Drug No  
RX/OTC/DISCN: RX  
TE Code:

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Active Ingredient:	CANDESARTAN CILEXETIL
Dosage Form;Route:	Tablet; Oral
Proprietary Name:	ATACAND
Applicant:	ASTRAZENECA
Strength:	32MG
Application Number:	020838
Product Number:	004
Approval Date:	Jun 04, 1998
Reference Listed Drug	Yes
RX/OTC/DISCN:	RX

TE Code:

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020838	001	5703110	APR 18 2011	
020838	001	5705517	APR 18 2011	

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020838	001	NCE	JUN 04 2003

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